IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants

: Keisuke INOUE et al.

Group Art Unit: 1615

2004 #Appl. No.

: 10/849,778

Examiner: Not Yet Assigned

Filed

: May 21, 2004

Confirmation No.: 1104

For

: CARBOXYLIC COMPOUND AND MEDICINE COMPRISING THE

SAME

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
U.S. Patent and Trademark Office
220 20th Street S.
Customer Window, Mail Stop
Crystal Plaza Two, Lobby, Room 1B03
Arlington, VA 22202

Sir:

In accordance with the duty of disclosure under 37 C.F.R. §1.56 and §§1.97-1.98, Applicants hereby call to the Examiner's attention the following documents:

- (1) Expert Opinion on Investigational Drugs, "Insulin Sensitiser Drugs," Vol. 9, No. 6, pp. 1347-1361, 2000. Applicants note that this document is cited in the specification of the present application including page 1;
- (2) European Journal of Medicinal Chemistry, "ω-Substituted Alkyl Carboxylic Acids As Antidiabetic and Lipid-Lowering Agents," Vol. 33, pp. 775-787, 1998. Applicants note that this document is cited in the specification of the present application including page 2;
- (3) Metabolism, "BM 17.0744: A Structurally New Antidiabetic Compound With Insulin-Sensitizing and Lipid-Lowering Activity," Vol. 48, No. 1, pp. 34-40, January

- 1999. Applicants note that this document is cited in the specification of the present application including pages 2 and 29;
- (4) Journal of Medicinal Chemistry, "The Effect of 1,3-Diaryl-[1H]-pyrazole-4-acetamides on Glucose Utilization in ob/ob Mice," Vol. 44, pp. 2601-2611, July 6, 2001. Applicants note that this document is cited in the specification of the present application including page 29;
- (5) Journal of Clinical Investigation, "Glucose Transporter Levels in Spontaneously Obese (db/db) Insulin-resistant Mice," Vol. 85, pp. 962-967, March 1990. Applicants note that this document is cited in the specification of the present application including page 30;
- (6) Arznimittel-Forschung, "Effects of Pioglitazone on Glucose and Lipid Metabolism in Normal and Insulin Resistant Animals," Vol. 40, pp. 156-162, 1990.

 Applicants note that this document is cited in the specification of the present application including page 30;
- (7) Archives of Toxicology, "Species Differences in Induction of Hepatic Enzymes by BM 17.0744, An Activator of Peroxisome Proliferator-Activated Receptor Alpha (PPARa)," Vol. 73, pp. 440-450, 1999;
- (8) U.S. Patent No. 5,968,982 to VOSS et al., which issued on October 19, 1999. Applicants note that this application discloses subject matter related to compound A of the present application; and
- (9) U.S. Provisional Patent Application No. 60/472,737, which was filed on May 23, 2003 and is the parent of the present application. Applicants note that this provisional

application is a copy of the Japanese priority document of the present application, and thus a copy is not being provided herewith.

- (10) Applicants also bring to the Examiner's attention the following documents which were cited in U.S. Patent Application No. 10/500,463 (a copy of which is enclosed herewith), which discloses subject matter related to that of the present application:
- (11) Japanese Laid-Open Patent Publication No. 10-510515, which was published on October 13, 1998, together with a partial English language translation of the same; and
- (12) Japanese Laid-Open Patent Publication No. HEI 5-952, which was published on January 8, 1993, together with an English language Abstract of the same.

Further to the U.S. Patent and Trademark Office's decision to waive the requirement under 37 C.F.R. §1.98 (a)(2)(i), a copy of the U.S. patent (document 8) is not enclosed herewith. However, if a copy is needed, the Examiner is respectfully requested to contact the undersigned.

Applicants respectfully request that the Examiner consider the above material and cite the same. Copies of documents (1)-(7), (10), and (11) are attached hereto and documents (1)-(8), (10), and (11) are listed on the attached PTO-1449 Form. Applicants note that documents (9) and (10) are not listed on the PTO-1449 Form as they are unpublished documents. The Examiner is requested to initial the appropriate spaces on the attached Form and to return a copy of the completed Form to Applicants with the next official communication in the present application.

Applicants note that an Office Action on the merits has not issued in the present application, and thus no fee is believed necessary to ensure consideration of the submitted material. However, if an Office Action on the merits has issued and is crossing this

statement in the mail, the undersigned hereby authorizes the Commissioner to charge any fee necessary for the consideration of this statement, including any payment under 37 C.F.R. §1.17 (p) to Deposit Account No. 19-0089.

Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully Submitted, Keisuke INOUE et al.

Bruce H. Bernstein

Reg. No. 29,027

September 20, 2004 GREENBLUM & BERNSTEIN, P.L.C. 1950 Roland Clarke Place Reston, VA 20191 (703) 716-1191

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| FORM PTO-1449 ' ' ' | O.S. Department of Commerce Patent and Trademark Office | | Application No. 10/849,778 |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) | | Applicant Keisuke INOUE et al. | |
| | | Filing Date | Group |

May 21, 2004 1615 **U.S. PATENT DOCUMENTS** FILING DATE **DOCUMENT NUMBER** DATE **NAME CLASS SUBCLASS** IF APPROPRIATE 5 9 6 8 10/19/99 VOSS et al. 8 **FOREIGN PATENT DOCUMENTS** TRANSLATION **DOCUMENT NUMBER** DATE **COUNTRY CLASS SUBCLASS** YES NO 10/13/98 **JAPAN** 10 X 0 5 01/08/93 **JAPAN** 9 5 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) English Language Abstract of JP 5-952. Expert Opinion on Investigational Drugs, "Insulin Sensitiser Drugs," Vol. 9, No. 6, pp. 1347-1361, 2000. European Journal of Medicinal Chemistry, "ω-Substituted Alkyl Carboxylic Acids As Antidiabetic and Lipid-Lowering Agents," Vol. 33, pp. 775-787, 1998. Metabolism, "BM 17.0744: A Structurally New Antidiabetic Compound With Insulin-Sensitizing and Lipid-Lowering Activity," Vol. 48, No. 1, pp. 34-40, January 1999. Journal of Medicinal Chemistry, "The Effect of 1,3-Diaryl-[1H]-pyrazole-4-acetamides on Glucose Utilization in ob/ob Mice," Vol. 44, pp. 2601-2611, July 6, 2001. Journal of Clinical Investigation, "Glucose Transporter Levels in Spontaneously Obese (db/db) Insulin-resistant Mice," Vol. 85, pp. 962-967, March 1990. Arznimittel-Forschung, "Effects of Pioglitazone on Glucose and Lipid Metabolism in Normal and Insulin Resistant Animals," Vol. 40, pp. 156-162, 1990. Archives of Toxicology, "Species Differences in Induction of Hepatic Enzymes by BM 17.0744, An Activator of Peroxisome Proliferator-Activated Receptor Alpha (PPARa)," Vol. 73, pp. 440-450, 1999.

EXAMINER

DATE CONSIDERED

^{*}EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.